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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/513,151 | 02/25/2000 | Siegfried Hekimi | 979-1-017 | 7817 |

7590

10/02/2002

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/513,151

Applicant(s)

Hekimi et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 7-20 is/are pending in the application.
- 4a) Of the above, claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17 6) ☐ Other:

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claim 1 has been amended. Claims 2-6 have been canceled. Claims 1 and 7-20 are pending. Claim 1 is under consideration.

Claim Rejection Maintained.

3. The rejection of claims 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

(A)As drawn to the human homolog of the gro-1 gene of C elegans

Claim 1 is drawn to the polynucleotide of SEQ ID NO:3 which is the human homolog of the C elegans gro-1 gene. The specification teaches that the gro-1 gene and related genes are located in the gro-1 operon and express proteins that function at the level of cellular physiology and developmental rate and aging in C. Elegans. The specification teaches that the gro-1 genes are isolated from C. Elegans and that worms harboring a mutation in gro-1 (the e2400 mutation) have a longer life and an altered cellular metabolism relative to the wild type. The specification teaches that the predicted amino acid sequence encoded by the gro-1 transcript is highly similar to dimethylallyltransferase (pg. 13, lines 20-24) found in E. Coli and S. Cerevisiae. However, neither the specification nor any art of record teaches the properties of the human gro-1 proteins or the functioning of the gro-1-1 polypeptide as a mediator of development and aging in humans, or as a mediator in any other human disease. The specification provides no objective evidence that human individuals with a longer lifespan have mutations in the gro-1-1 protein or genes contributing to their longevity. The specification provides no objective evidence that induction of a mutation in a gro-1 gene can inhibit tumor growth. Furthermore, based on the similarity of gro-

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1 to dimethylallyltransferase, one of skill in the art would not know how to use the claimed gro-1 genes to alter longevity or to treat cancer as there is no direct relationship between dimethylallyltransferase and the cancerous state. Although gro-1 is a conserved gene in bacteria and lower eukaryotes, it does not necessarily follow that it is responsible for the same phenotype in higher mammals as in nematodes. Applicant has argues that there are numerous examples in the art where proteins carrying out similar biochemical functions in different genuses have similar effects on the organism. Applicant has filed an I.D. S. Consisting of numerous publications in which the mammalian homologue of a C elegans protein was demonstrated to be an ortholog, i.e. a protein having the same function as well as sequence homology. However, the examiner maintains that, although the disclosed polypeptide tRNA isopentenyl transferase in C elegans and tRNA isopentenyl transferase in humans, the effect of this tRNA on the growth and physiology of humans cannot be anticipated. Bork (Nature Genetics, 1998, Vol. 18, pp. 313-318) teaches that homology to a sequence does not establish the functional role of the protein and more often than not the cellular role of the protein in question differs from that of the detected homolog (page 315, second column, under the heading "Effects of noise on functional predictions").. Without further teaching and guidance from the specification, one of skill in the art would be subject to undue experimentation in order to use the claimed teachings regarding the gro-1-1 (SEQ ID NO:3) polynucleotide on complex multicellular vertebrates such as humans as the function of human homolog cannot be anticipated based on the function of the C elegans genes.

(B)As drawn to functional fragments of human gro-1

Claim 1 is drawn to functional fragments of the human gro-1 gene. The specification describes a method for the screening of functional fragments of the C elegans gro-1 gene based on a rescue of the e2400 mutant phenotype which exhibits a reduced rate of development and aging. However, the specification does not describe a method or assay to determine or screen for functional fragments of the human gro-1 gene.

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4. All other rejections and objections as stated in Paper no. 12 are withdrawn.


Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
October 1, 2002


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